Congress of the United States

Washington, DC 20515

December 11, 2012

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We are writing to express concern about the Food and Drug Administration's (FDA) lack of progress investigating and taking action to protect workers and consumers from the serious health impacts resulting from the use of methylene glycol (a liquid form of formaldehyde) in hair straightening treatments such as Brazilian Blowout.

In October 2010, after receiving several complaints from hair stylists that the use of two hair straightening products known as Brazilian Blowout Solution and Acai Professional Smoothing Solution were causing acute adverse health impacts, the Oregon Occupational Safety and Health Division (Oregon OSHA) and the Oregon Health and Science University conducted testing that revealed that these products contained between 4.85% and 10.6% formaldehyde, much higher than the 0.1% threshold of the OSHA Formaldehyde Standard.[1] Some of the highest formaldehyde levels were found in the Acai Professional Smoothing Solution, which was labeled "formaldehyde-free." Subsequent air monitoring of salons by the federal Occupational Safety and Health Administration (OSHA) led the agency to issue a Hazard Alert, warning salons not to use formaldehyde-based hair straighteners and outlining strict requirements salons must follow if they want to continue their use.[2]

Following OSHA's alert, on May 6, 2011, we sent a letter to FDA highlighting the complaints raised about formaldehyde in hair straightening products and the warnings issued by OSHA. In the letter we requested that FDA take quick decisive action to protect consumers by initiating a voluntary recall of brands like Brazilian Blowout Solution and Acai Professional Smoothing Solution and instituting better labeling practices and warnings for hair straighteners containing formaldehyde. The letter also called on FDA to conduct a review of whether formaldehyde and formaldehyde-releasing chemicals should be banned due to their health risks.

In August 2011, the FDA sent a warning letter to the makers of Brazilian Blowout (GIB LLC) alerting the company that the Brazilian Blowout Acai Professional Smoothing Solution was considered by the agency to be adulterated and misbranded under federal law. Specifically, the FDA stated, "Brazilian Blowout is an adulterated cosmetic because it bears or contains a deleterious substance [methylene glycol] that may render it injurious to users under the conditions of use prescribed in your labeling."[3] In addition, the agency warned the company that

---

[1] Oregon OSHA and CROET 2011. Keratin-Based Hair Smoothing Products and the Presence of Formaldehyde. Available: http://www.orosha.org/pdf/Final_Hair_Smoothing_Report.pdf

[2] http://www.osha.gov/SLTC/formaldehyde/hazard_alert.html

[3] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm

the product was misbranded because, "Brazilian Blowout contains the liquid form of formaldehyde, methylene glycol; however, the product label declares that the product contains 'No Formaldehyde' or is 'Formaldehyde Free.'"

Despite FDA's warning letter, GIB LLC has refused to reformulate Brazilian Blowout Acai Professional Smoothing Solution to eliminate or reduce the levels of formaldehyde in the product. In fact, the same month that FDA issued its warning letter, the company sent letters to salons reaffirming the safety of its product and offering a new loyalty program. In addition to reiterating the safety of the original Brazilian Blowout Solution, the company has also launched a new product known as Zero+ Solution, which the company claims is a "new and improved" system with "0% Formaldehyde released before, during or after the treatment." To date, FDA has not publically taken any additional enforcement action against this company or substantiated the company's statement regarding the safety of original Brazilian Blowout solution or the claims made regarding the company's new Zero+ product.

In January 2012, the California Attorney General's office reached a class-action settlement with the makers of Brazilian Blowout that required the company to stop deceptive advertising practices and put caution stickers on the product warning that it can release formaldehyde gas. In response to the settlement, the chief executive of GIB LLC, Michael Brady, stated, "We get to sell the product forever without reformulation." He said, "In my eyes, that's the acquittal we've been waiting for."[4]

Formaldehyde exposure in salons is a serious concern to the health and safety of salon workers and patrons. The Environmental Protection Agency (EPA) has classified formaldehyde as a probable carcinogen and the International Agency for Research on Cancer has identified it as a known human carcinogen. Recently, the National Academy of Sciences confirmed the EPA's determination that formaldehyde causes cancer in humans.[5] In addition, the National Cancer Institute, the World Health Organization, and the National Toxicology Program have all identified a possible link between formaldehyde exposure and leukemia.[6] Furthermore, because of concern about formaldehyde, Canada, Ireland and Australia have all banned the distribution of Brazilian Blowout.

The FDA's inaction on this matter is putting the health of thousands of salon workers and consumers at risk of dangerous formaldehyde exposure from the continued use of not only Brazilian Blowout, but other hair straightening treatments that contain formaldehyde. A November 2011 study published in the *Journal of Occupational Environmental Hygiene* found dangerous levels of formaldehyde in several other brands of hair straighteners.[7]

The FDA has an obligation to protect the public health by using its legal authority to ensure cosmetic products such as Brazilian Blowout Acai Professional Smoothing Solution that are clearly adulterated or misbranded are removed from the market. To understand better the

---

[4] http://www.nytimes.com/2012/03/06/business/brazilian-blowout-agrees-to-a-4-5-million-settlement.html?_r=0

[5] National Academy of Sciences "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde" http://www.nap.edu/catalog.php?record_id=13142

[6] National Academy of Sciences 2011. Review of the Environmental Protection Agency's IRIS Assessment of Formaldehyde. Available: http://www.nap.edu.catelog.phb?record_id=13142

[7] Pierce, J., Abelmann, A., Spicer, L., Adams, R., Glynn, M., Neier, K., Finley, B., & Gaffney, S. (2011). Characterization of formaldehyde exposure resulting from the use of four professional hair straightening products. *Journal of Occupational Environmental Hygiene*, *8*(11), 686-699.

actions that FDA has taken regarding this matter, we respectfully ask for your response to the following questions:

1. Does the FDA still believe, as stated in its August 21, 2011 warning letter that Brazilian blowout is adulterated because it contains methylene glycol, which releases formaldehyde at levels that could pose harm under conditions of its prescribed use? If yes, what subsequent action has FDA taken to protect the public from this product? If not, why not?
2. In FDA's warning letter, GIB LLC, the makers of Brazilian Blowout, were instructed to make immediate changes to address the adulteration and misbranding violations or face additional enforcement actions "including, but not limited to, seizure and/or injunction." Has the FDA initiated additional enforcement actions against this company? Please explain and provide all relevant documentation to support your answer.
3. FDA's warning letter also instructs GIB to provide a written response within 15 days to the agency as to the specific steps taken to address the violations of adulteration and misbranding. Did GIB respond to FDA's warning letter? Is it FDA's opinion that the company has adequately addressed the violations noted in the warning letter? Please provide all documents or other records (including memos, emails, meeting minutes, letters and other communications) to support your answer.
4. The makers of Brazilian Blowout have launched a new product that they advertise as containing "0% Formaldehyde released before, during or after the treatment." Has the FDA evaluated this claim and the company's labeling practices to determine whether this product may also be considered adulterated and or misbranded? Has the FDA asked GIB LLC to provide testing data to substantiate the safety of any of its hair straightening products? If yes, what has the FDA determined based on this submitted data? If not, why not?
5. In our May 2011 letter, we asked FDA to look more generally into hair straightening products on the market and conduct testing to determine whether other cosmetic manufacturers were producing products that may similarly contain dangerous levels of formaldehyde. Please provide an update on FDA's actions on this request including the number of products evaluated and determinations made as well as a plan and timeline for how FDA will continue to address this request.
6. In FDA's warning letter to GIB, LLC, the agency makes note that these hair straightening products are not only used in salon settings, but may also be used in the home since they are sold on the internet and in beauty retail stores to the general public. Does the FDA believe it is appropriate for these types of formaldehyde-containing hair straightening products to be used by unlicensed professionals in a home setting that may not have the ventilation systems frequently present in salons? Has the FDA taken any steps to ensure that all such products contain appropriate warnings so that consumers are aware of the dangers of using such a product outside a salon setting such as in the home?
7. In July 2011, the Cosmetic Ingredient Review Expert Panel (CIR), the industry-funded body tasked with reviewing the safety of ingredients in cosmetics, reaffirmed that formaldehyde and its equivalents are not safe in cosmetic products at concentrations greater than 0.2% and tentatively concluded that the safety of products where

formaldehyde is released as a gas could not be determined.[8] What is FDA's process for evaluating the safety of a cosmetic ingredient when it has already been deemed to be unsafe by industry's ingredient review board?

Thank you for your assistance and cooperation in this important matter. We ask that you provide a full and complete response no later than close of business on December 21, 2012. Should you have any questions about this request, please have your staff contact Dr. Avenel Joseph of Rep. Markey's staff at 202-225-2836 or Megan Michaud of Rep. Schakowsky's staff at 202-225 -2111.

Sincerely,

Rep. Edward J. Markey
Member of Congress

Rep. Jan Schakowsky
Member of Congress

Rep. Earl Blumenauer
Member of Congress

Cc: Linda Katz
Director
Office of Cosmetics and Colors (OCAC)
U.S. Food and Drug Administration

[8] http://www.cir-safety.org/ingredient/formaldehyde